

REMARKS

The pending Office Action addresses claims 1-20, rejecting claims 1-8 and 20; claims 9-19 have been withdrawn and are cancelled herein.

Amendments Presented

In this Amendment, four independent claims are presented: claims 1, 8, 20, and 29, with independent claims 1, 8, and 29 to be amended or new as follows:

Claim 1 has been amended to positively incorporate the “first and second lengths” of suture and to indicate the location of the first and second lengths of suture on the suture contacting element.

Claim 8 has been amended to incorporate the features previously presented in claim 1, transforming claim 8 from a dependent claim to an independent claim. Claim 8 also has been amended to clarify that the piston acts to “move” the first and second lengths of suture “into contact with” at least one electrode. This clarification is consistent with the invention description (Page 11, lines 21-24).

Claim 29 is a new independent claim that includes the features previously presented in claim 1 and also specifies that the suture contacting element have “at least one pod configured to prevent the first and second sutures from sliding off the suture contacting element.” This specification is consistent with the invention description (Page 8, lines 6-10).

New dependent claims, 21-28 and 30-34, have also been added. Each of these recites one or more features already present in the original claims, new independent claim 29, or, in the case of claims 27 and 33 which recite that the suture contacting element places the first and second lengths of suture into close physical contact, in the description of the invention (Page 9, lines 16-18).

As all of the amendments and additions merely apply features already present in the claims and invention description, no new matter is added. Upon entry of this Amendment, claims 1-8, and 20-34 will be pending.

Rejections under 35 U.S.C. §102

The Examiner has made claim rejections over three separate references as described below.

The Rejection over Morris

The first rejection is over Morris (US 6,488,690). Morris discloses a hand-held instrument that coagulates suture knots for enhanced security. The instrument incorporates a fork-shaped, knot-retaining feature with a channel that enables a strand of suture to be dressed away from the tip when heated. The suture knot, which is tied prior to being placed in the device so that only one length of suture is provided, is sealed by a heating element located at the tip of the tool. The Examiner rejects claims 1, 5, 7, and 20 under 35 U.S.C. §102(e) as being anticipated by Morris. More specifically, the Examiner argues:

Regarding Claim 1, 7, and 20, Morris discloses a suture welding system [Column 2, lines 27-33] for fixedly attaching a first length of suture to a second length. Morris also discloses a method of using his welding system. Morris discloses an electrosurgical energy source [Column 3, lines 13-17: “power-supply”], a suture welding device (100) [see Fig. 1], a working end (distal end of device 100), and a suture contacting element (108). Morris discloses both unipolar and bipolar arrangements for his electrodes [Column 3, lines 10-13].

In his bipolar arrangement [Figure 1], he discloses a first electrode (first wire) electrically coupled to the power supply (a battery or other form of power) disposed on the contacting element (108) for providing electrical energy to the suture [Column 3, lines 10-29]. As a part of his bipolar configuration, Morris also discloses a second electrode (second wire) coupled to the battery, which provides a return energy path to the battery. Specifically, Morris describes a “pair of insulated wires” [Column 3, lines 26]. Those of ordinary skill in the welding art know that a “bipolar” configuration refers to an arrangement in which current travels from one electrode to another as a part of a complete circuit. Suture is put in the gap between the two electrodes and two lengths are attached to each other [Column 2, lines 38-48]. Figures 1 and 2 show the suture in contact with the suture contacting element (108). Although the respective locations of the tips of the wires are not clear from the disclosure, the suture is certainly capable of being placed between them. Figure 1 shows the suture between

two grasping members and it can be assumed that one wire is in each grasper.

For the following reasons, the claimed invention is not anticipated by Morris.

Claim 1 has been amended to incorporate the first and second lengths of suture as elements of the claimed suture welding system. This amendment distinguishes the claimed invention from Morris because Morris does not use first and second lengths of suture. In Morris, the sutures are tied into a knot prior to being placed in the sealing device, thus creating a single knotted length. In the claimed invention, the first and second lengths of suture are individually placed onto the suture contacting element prior to welding. Thus, the claimed invention is distinguished from Morris because it utilizes two distinct lengths of suture whereas Morris utilizes only one.

Claim 20 should be allowed over Morris. Although claim 20 has not been amended, it is patentable over Morris for essentially the same reasons as Amended claim 1. Claim 20, a method claim, states that the first and second lengths of suture are placed into contact with the suture contacting element. As stated above, in Morris, the suture is tied into a knot prior to being placed in the sealing device. In fact, the stated purpose of Morris is merely to secure a previously-tied suture knot – not to provide an alternative to the traditional practice of tying suture knots, as is provided by the suture welding system in the claimed invention. Similarly to Amended claim 1, claim 20 should be allowed over Morris because the claimed method utilizes two distinct lengths of suture whereas Morris utilizes only one.

Amended claim 8 should be allowed over Morris. Claim 8 has been amended to incorporate the features previously presented in claim 1 and to clarify that the piston acts to move the first and second lengths of suture into contact with at least one electrode. The Examiner did not reject to the original claim 8 with respect to Morris; thus, Amended claim 8 should also be allowed over Morris because the amendments only further distinguish the claimed invention from Morris.

Claim 29, a new independent claim, should be allowed over Morris. Claim 29 includes the elements previously presented in claim 1 and also specifies that the suture contacting element have at least one pod configured to prevent the first and second lengths of suture from sliding off

the suture contacting element. Morris does not include any pods; the suture is held in place by the knot. Thus, the claimed invention is distinguished from Morris because it employs pods to secure the first and second lengths of suture whereas Morris uses the knot itself to hold the single length of suture in place. Therefore, claim 29 should be allowed over Morris.

The Rejection over Tetzlaff

The second rejection is over Tetzlaff (US 6,277,117). Tetzlaff discloses mechanical forceps capable of sealing open vessels. The forceps have a removable electrode assembly located at one end and a handle for effecting movement at the other. The forceps' electrode jaws have a smooth clamping surface. The Examiner rejects claims 1, 3, and 4 under 35 U.S.C. §102(e) as being anticipated by Tetzlaff. More specifically, the Examiner argues:

Regarding Claim 1, Tetzlaff discloses a welding device capable of welding suture having two electrodes (110/120), an energy source ("electrosurgical generator") [Column 6, lines 31-33], and a suture contacting element [Column 1, lines 34-42]. His invention is intended for use in welding body tissue, but is certainly capable of welding suture as well.

Regarding Claims 3 and 4, Tetzlaff discloses two opposing faces ("prongs") having a variable gap between them. Each face has an electrode (110/120) on top of it [Figure 2; Column 2, lines 41-48; Column 7, lines 49-58]. Although the stop member (106) [see Fig. 4 especially] prevents the electrodes from touching each other, lengths of suture are capable of being placed between the two electrode surfaces and held there.

For the following reasons, the claimed invention is not anticipated by Tetzlaff.

Amended claim 1 should be allowed over Tetzlaff. Claim 1 has been amended to positively incorporate the first and second lengths of suture as elements of the claimed suture welding system. This amendment distinguishes the claimed invention from Tetzlaff because Tetzlaff does not describe welding lengths of suture. In fact, the stated purpose of Tetzlaff is to seal open vessels; thus, suture is never associated with the device. The Examiner appears to agree as he did not reject claim 20, a method claim that positively recites placing two lengths of suture on the device, with respect to Tetzlaff. As claim 20 and Amended claim 1 both recite the same lengths of suture, Amended claim 1 should be allowed over Tetzlaff.

Amended claim 8 should be allowed over Tetzlaff. Claim 8 has been amended to incorporate the features previously presented in claim 1 and to clarify that the piston acts to move the first and second lengths of suture into contact with at least one electrode. The Examiner did not reject to the original claim 8 with respect to Tetzlaff; thus, Amended claim 8 should also be allowed over Tetzlaff because the amendments only further distinguish the claimed invention from Tetzlaff.

Claim 29, a new independent claim, should be allowed over Tetzlaff. Claim 29 includes the elements previously presented in claim 1 and also specifies that the suture contacting element have at least one pod configured to prevent the first and second lengths of suture from sliding off the suture contacting element. Tetzlaff has a smooth contacting surface that does not include pods. The stated purpose of Tetzlaff is to seal open vessels; thus, pods for preventing the movement of suture are not necessary. Therefore, the claimed invention is distinguished from Tetzlaff because it employs pods to secure lengths of suture whereas Tetzlaff uses a smooth jaw member.

The Rejection over Rydell

The third rejection is over Rydell (US 5,342,359). Rydell discloses a bipolar coagulation device comprised of three concentric tubes. Translational movement of the inner tube causes the electrode jaws to come into contact with each other. When tissue is grasped within the closed jaws the electrodes act to perform the cauterization. The Examiner rejects claims 1, 2, and 8 under 35 U.S.C. §102(b) as being anticipated by Rydell. More specifically, the Examiner argues:

Regarding Claim 1, Rydell discloses a system capable of welding suture having two electrodes (34/36) [Column 4, lines 65-66], an energy source ("energy source – see Abstract), and a suture contacting element (distal end of device). His invention is intended for use in welding body tissue, but is certainly capable of welding suture as well. Rydell discloses a "bipolar" instrument, which means that one of the electrodes will provide electrical current and the other will provide for return of the current to the source when the two electrodes come in contact with each other.

Regarding Claim 2, Rydell's device uses radio frequency waves [Column 8, lines 1-10; Column 5, lines 58-60].

Regarding Claim 8, with reference to Figure 4B, Rydell's device has a piston (16) that slides and is able to engage suture positioned in the distal hollow of component 34. The piston slides from the position shown in Fig. 4A to the position shown in Fig. 4B [Column 5, lines 24-27].

For the following reasons, the claimed invention is not anticipated by Rydell.

Amended claim 1 should be allowed over Rydell. Claim 1 has been amended to incorporate the first and second lengths of suture as elements of the claimed suture welding system. This amendment distinguishes the claimed invention from Rydell because Rydell does not describe welding lengths of suture. In fact, the stated purpose of Rydell is to cauterize tissue; thus, suture is never associated with the device. The Examiner appears to agree as he did not reject claim 20, a method claim that positively recites placing two lengths of suture on the device, with respect to Rydell. As claim 20 and Amended claim 1 both recite the same lengths of suture, Amended claim 1 should be allowed over Rydell.

Amended claim 8 should be allowed over Rydell. Claim 8 has been amended to incorporate the features previously presented in claim 1 and to clarify that the piston acts to move the first and second lengths of suture into contact with at least one electrode. This amendment distinguishes the claimed invention from Rydell. In Rydell, the piston acts to close the electrode jaws. In the claimed invention, the piston merely moves the first and second lengths of suture into contact with at least one electrode; the piston does not act to bring the electrodes into contact with each other. Thus, Amended claim 8 should be allowed over Rydell because the amendments only further distinguish the piston in the claimed invention from the piston in Rydell.

Claim 29, a new independent claim, should be allowed over Rydell. Claim 29 includes the elements previously presented in claim 1 and also specifies that the suture contacting element have at least one pod configured to prevent the first and second lengths of suture from sliding off the suture contacting element. Rydell has a smooth contacting surface that does not include pods. The stated purpose of Rydell is to cauterize tissue; thus, pods for preventing the movement of suture are not necessary. Therefore, the claimed invention is distinguished from Rydell because it employs pods to secure lengths of suture whereas Rydell uses a smooth electrode jaw member.

Rejections under 35 U.S.C. §103

The Examiner has rejected the claimed invention over Morris (US 6,488,690) in view of Doddi (US 4,052,988). Morris discloses a hand-held instrument that coagulates suture knots for enhanced security, while Doddi discloses synthetic absorbable sutures made from polymers. The Examiner rejects claim 6 under 35 U.S.C. §103(a) as being unpatentable over Morris in view of Doddi. More specifically, the Examiner argues:

Morris does not disclose making suture out of polydioxanone, but Doddi teaches that one ought to make suture for use in the body out of polydioxanone because it has many desirable properties, including strength, smoothness, and pliability. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to make Morris' suture out of polydioxanone because this material has many surgically desirable properties such as tensile strength and pliability, as taught by Doddi.

For the following reasons, the combination of Morris and Doddi fails to render the claimed invention obvious.

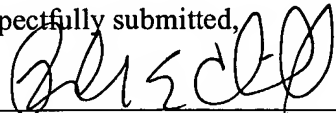
Claim 6 should be allowed, in addition to the fact that it depends from claim 1, because it is not obvious in view of Morris and Doddi. Claim 6 discloses first and second lengths of suture made of polydioxanone. Doddi teaches that the physical properties of polydioxanone make it a smart choice for suture material. In view of Doddi, however, it is not obvious that polydioxanone can be used in conjunction with Morris. The heating element in Morris is not capable of welding polydioxanone. In fact, the claimed invention is the first suture welding device to employ radio frequency waves in order to facilitate welding of polydioxanone sutures. The Examiner also should note that although Rydell employs radio frequency energy, the claimed invention is not obvious in view of Rydell and Doddi. While Rydell uses RF energy, the stated purpose of Rydell is to cauterize tissue – not to weld suture. Thus, Rydell and Doddi cannot teach or suggest that lengths of polydioxanone suture can be used with a suture welding device. Therefore, claim 6 should be allowed over Morris, Rydell, and Doddi for this additional reason.

Conclusion

In view of the above, each of the presently pending claims in this application is in condition for immediate allowance. If the Examiner believes that further communication would expedite allowance of these claims, Applicant requests that the Examiner contact the undersigned attorney at the Examiner's convenience.

Dated: June 18, 2004

Respectfully submitted,

By 

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